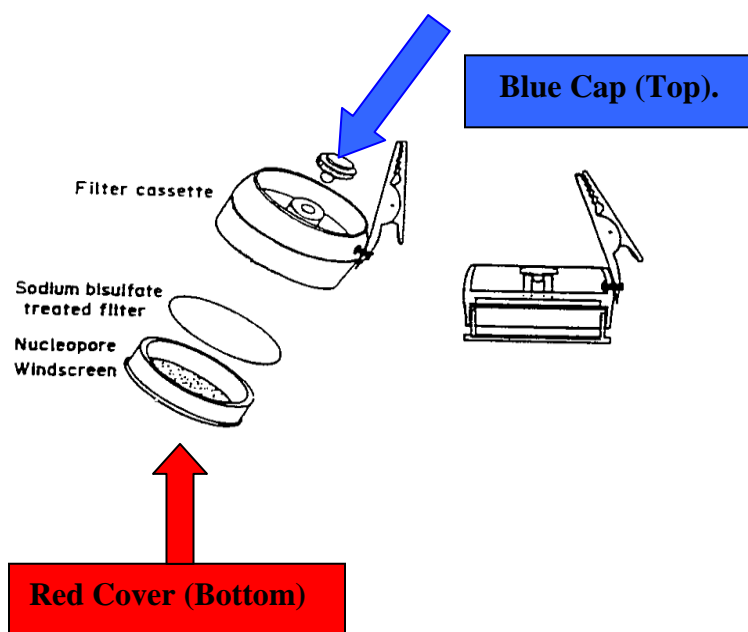


IV. NICOTINE MONITOR COLLECTION AND SHIPPING TO LAB

After completing the *Nicotine Monitor Placement and Safety Observation Determination Form* with the mother (as described in **Chapter III**), you can then place the monitors in the specified locations. Nicotine monitoring in the study homes will be done using passive samplers for vapor-phase nicotine. The purpose of chapter is to provide instructions for the correct placement and monitoring of secondhand tobacco smoke in homes. In general, these procedures will cover proper handling, placement, storage and shipping of the nicotine monitors.

A. Description of Nicotine Air Monitors

Monitoring in the study homes will be done using passive samplers for vapor-phase nicotine. The monitors to be employed in the ETS study look as follows:



Each air monitor weighs 16 grams and has a blue cap (top) and red cover (bottom) to protect the monitor from ambient air coming into the monitor. The three primary parts of a vapor-phase nicotine passive monitor include:

- 1) **The Filter cassette:** This is the most solid part of the monitor. It is made with polystyrene (plastic). It has a clip at the top end that will be very useful to correctly place the monitor. In the inferior part you can find a pad to support the filter.
- 2) **The Filter:** The filter is treated with sodium bisulfate. It is able to store the nicotine that is filtered from the household environment. This filter will be carefully separated from the rest of the sampler in the lab, where the level of nicotine will be analyzed using gas-chromatography.

- 3) **The Nucleopore Windscreen:** This is the most delicate part of the sampler. The windscreen protects the filter and lets the air pass through it to allow the environmental nicotine to reach the filter. The size of the pores in the windscreen allows for the passage of nicotine at a specific rate (i.e., the flow rate is equal to 0.024 liters per minute). The amount of air nicotine in the household is calculated based upon this flow rate + the time the nicotine monitor is placed within a home. ***Therefore, if the windscreen is broken in the process of removing the red cover (bottom), or while placing the monitor, another nicotine monitor must be used.***

For the ETS study, each monitor will be stored in a plastic baggie which is placed inside a plastic cup (similar to a urine cup) for its transport and protection.

B. Types of Monitoring for ETS Study

For the ETS main and pilot study activities, up to five different monitors may be left in the participant's home; each monitor serves a different purpose as described below.

- 1) The ***“primary”*** monitor (P) is the primary source of information about environmental tobacco smoke. This monitor will be placed in all homes at each assessment interval, and will be left in the home across a 7-day interval. *The primary monitor will be placed in the room where the baby is most likely to be exposed to cigarette smoke OR, if no such room exists (e.g., no one smokes inside the home), then the monitor will be placed in the room where the baby is most likely to spend his/her time during the day.*
- 2) The ***“duplicate”*** monitor (D) will be placed adjacent to the “primary” monitor and left in the home for the same 7-day period. This monitor is used for quality control purposes and will be placed in a 5% sub-sample of the home visit assessments.
- 3) The ***“blank”*** (B) monitor is carried into the field to assess whether the nicotine air monitors are being properly handled. This monitor, which will be opened and closed adjacent to the placement of the “primary” monitor and then immediately removed, is collected for a 10% sub-sample of the home visit assessments. The blank monitor is a quality control procedure that informs JHU investigators as to whether the samples are being handled properly in the field (e.g., in the car, at each home). For example, if the Home Visitor smokes on the way to a home or does not follow recommended handling procedures, then this monitor will detect the extent of those errors in nicotine measurement. The blank monitor sampler is very important for the analysis, since the nicotine levels in the primary monitor will be corrected for the levels found in the blank monitor.
- 4) The ***“longer-term”*** (LT) monitor will be placed in the home in a room other than the “primary” room at baseline, and remain in the home for the duration of the study. This monitor is designed to counter the reactive effects (e.g., people smoking less) of the temporary, 7-day monitors. *This monitor will be placed in*

*the room where the most cigarette smoke is likely to occur OR, if that room happens to be the same room where the baby is most likely to be exposed, the LT monitor will be placed in the room where the second most cigarette smoking is likely to occur. If no such room exists (e.g., no one smokes inside the home), then the LT monitor is placed in the room where the household members spend most of their time during the day. **Be aware that the LT monitors look different than the other monitors.** They will be placed in plastic urine cups that have an orange dot on them, and they will also have red plugs at the top and red bottoms, instead of the blue plugs at the top and red bottom covers that will be used for the “primary”, “duplicate”, and “blank” monitors.*

- 5) An “**extra**” monitor (E) will be placed in each home in the same room as the LT monitor at the baseline visit. The location of the extra monitor for the postpartum visit may change if the mother indicates there is a change in the room where the baby is most likely to be exposed to smoke or the room where the baby spends most of his/her time. This monitor will help us determine whether we have selected the best locations for the “primary monitor.” This monitor is the same as the “primary,” “duplicate,” and “blank” monitors, that is, it will have a blue top and red bottom.

C. Criteria and Questions to Determine Placement of Nicotine Monitors

The specific criteria and questions for determining which rooms to place the primary and long-term monitors (which in turn guide the placement of the other monitors) are listed below. To determine the appropriate rooms, you will need to refer to the mother’s answers to the questions in the *Nicotine Monitor Placement and Safety Observation Determination Form*.

1. Primary, Duplicate, and Blank Monitor Placement Criteria

During the baseline and postpartum home visits, selection of the room for the primary monitor is based on the criteria listed below and the mother’s responses to the questions in the **baseline** version of the *Nicotine Placement and Safety Observation Determination* questionnaire. If the participant’s home is selected for quality control purposes (see **Section E.2** below), the placement of the blank or duplicate monitor will be the same as the primary monitor.

Criteria #1: Room where the newborn baby will be most often exposed to ETS in the home:

Q17. Of all the rooms where your baby will spend time after you give birth, in which room of your house will your newborn baby be most often exposed to cigarette smoking?

OR, IF THE MOTHER SAYS “DK,” OR “NO ONE WILL SMOKE IN MY HOUSE,” OR “MY BABY WILL NOT BE EXPOSED TO SMOKE IN MY HOUSE OR ANY PARTICULAR ROOM,” ETC. THEN GO TO CRITERIA #2.

Criteria #2: Room where newborn baby will spend most of his or her time during the day:

Q12. After you give birth, where will your baby spend most of his/her time during the day?

2. Long-Term Monitor Placement Criteria

During the baseline home visit, selection of the room for the long-term monitor is based on the criteria listed below and the mother's responses to the questions in the **baseline** version of the *Nicotine Placement and Safety Observation Determination* questionnaire. The long-term monitor will remain in this room until the 12 month home visit assessments (i.e., for the duration of the study).

Criteria # 1: Room in which cigarette smoking is most likely to occur:

Q9. In which room would you say that the most cigarette smoking occurs?

OR, IF THIS ROOM IS THE SAME ROOM AS WHERE YOU PLACE THE PRIMARY MONITOR, THEN GO TO CRITERIA #2.

Criteria # 2: Room in which cigarette smoking is second most likely to occur:

Q10. In which room would you say that the second most cigarette smoking occurs?

OR, IF THE MOTHER SAYS "DK," OR "NO ONE WILL SMOKE IN MY HOUSE," OR "NO ONE SMOKES IN ANY PARTICULAR ROOM," ETC. THEN GO TO CRITERIA #3.

Criteria # 3: Room where household members spend most of their time during the day:

Q7. In which room do other members of your household spend most of their time during the day?

3. Extra Monitor Placement Criteria

During the baseline home visit, placement of the extra monitor will be the same as the long-term monitor. The location of the extra monitor may change, however, for the postpartum visits. Specifically, *for the postpartum visits*, if the mother indicates in the postpartum version of the *Nicotine Monitor Placement and Safety Observation Determination Form* that the room where the baby spends most of his or her time during the day (Q. #17) room has changed since baseline, OR the room where the baby is most often exposed to cigarette smoke (Q. #20) has changed, then the placement of the extra monitor will be in the new room. If both of these rooms have changed, and the rooms do not match each other (i.e., the mother gives different responses for both Q. #17 and Q. #20), then place the extra monitor in the new room where the baby is most likely to be exposed to cigarette smoke (Q. #20).

D. Contents of the Air Nicotine Monitor Kits

The Home Visitor will need an Air Nicotine Monitor Kit for each home visit. A tool box or some other type of kit that will house the following materials will be used for traveling back and forth to homes to place the nicotine monitors. The key components of the Air Nicotine Monitor Kits include:

- Four unused “live” air nicotine monitors (with blue plugs/tops); each placed individually in a plastic baggie which is then placed inside a urine cup
- One unused “long-term/fake” air nicotine monitor (with a red plug/top) placed inside a plastic baggie which is then placed inside a urine cup that contains an orange dot.
- Blank labels (JHU will send with monitors)
- Plastic surgical gloves (powder-free for handling monitors)
- Extra plastic baggies (to use in case the plastic bags which hold the monitor break)
- Tape (to hang monitors or hold in place; not scotch tape but some other tape that can be used to secure the monitors that is not too sticky as to leave marks in the home, but is secure enough to hold the weight of a monitor if for example it were to be taped onto something)
- String (to hang monitors or hold in place)
- Scissors (to cut string)
- Ballpoint pen (for writing on labels and forms)
- Measuring tape (50’ tape)
- Calendar and/or Atomix Clock/Watch (automatically set to the US Government's National Institute of Standards and Technology (NIST), the official timekeeper for the US located in Boulder, Colorado, to display the correct date/time).
- Extra batteries for the Atomix watch/clock
- Car refrigerator (powered by cigarette lighter)
- FOR HOME VISIT B ONLY: Empty urine cups and red caps (bottoms) from Home Visit A

Either in the Air Nicotine Monitor Kit or elsewhere, the following ETS study forms are needed:

- *ETS/Nicotine Monitor Drop Off Form* (FOR BOTH HOME VISIT A AND B)
- *ETS/Nicotine Monitor Pick Up Form* (FOR HOME VISIT B ONLY)
- *Nicotine Monitor Sample Sheet*
- *Map of House and Rooms: Drawing/Data Form* (baseline)
- *Nicotine Monitor Placement and Safety Observation Determination Form* (baseline)

The Home Visitor responsibilities with support from the Site Coordinator (Prag Katta) and Purchasing Coordinator (Bunmi Sumby) will include the following:

- To order monitors and labels from JHU.
- To store the monitors in a safe place at the GWU offices,
- To place them in and pick them up from the respective participant homes,
- To complete assessment monitoring protocols (e.g., DMS, Sample Sheets, Excel files) and keep track of the data collection forms and codes, and
- To prepare monitors for shipment on a regular basis.

E. Preparatory Steps for Placing the Nicotine Air Monitors during Home Visit A

1. Selecting the Rooms for Placing the Primary and Long-term Monitors

During baseline Home Visit A, after you have drawn a map of the home (see *Chapter III*) and you have completed the *Nicotine Monitor Placement and Safety Observation Determination Form*, you will select the room(s) where the air nicotine monitors will be placed. For all post-partum home visit assessments, the location of the monitors will be the same as the baseline with the possible exception of the extra monitor (as discussed above and in more detail in *Section F.3* below). Also, if the family has moved, you will need to select new rooms/locations for the monitors based on (1) the criteria listed above and (2) the mother's answers to the postpartum *Nicotine Monitor Placement and Safety Observation Determination*.

2. Completing/Updating Nicotine Monitor Sampling Sheet to Determine the Need for a Blank or Duplicate Monitor

As noted above, a duplicate monitor will be placed next the primary monitor for 10% of the cases, and you will collect a blank monitor sample in the same room and location of the primary monitor for 5% of the cases. To keep track of when a duplicate and blank monitor are needed, you will complete and update the *Nicotine Monitor Sampling Sheet* during each home visit when monitors are being placed inside the home. An example of a *Nicotine Monitor Sampling Sheet* is included at the end of this chapter. Specifically, each time you place a primary monitor in a home, you will need to refer to the next available row in the Sampling Sheet and add the subject ID number and date the monitor is being placed in the home to columns B and D, respectively. If the row is yellow-shaded, this indicates that a duplicate is required, if the row is grey-shaded, a blank sample must be collected. You will then write the subject ID number, the JHU monitor ID number, and the date the duplicate monitor was placed in the home or the blank sample was collected in the row directly below (which will also be either yellow or grey-shaded). Notice that in the row, Column D will indicate the type of monitor to be placed (i.e., either "B" for a blank monitor or "D" for a duplicate monitor).

3. Creating the ETS Nicotine Assessment ID Numbers and Labels

The correct identification of the nicotine monitors is very important. Each monitor will come with a unique Johns Hopkins University (JHU) monitor ID number which will be affixed to the top of the device. The JHU ID label will be on the top of the monitor near to the alligator clip on the rim.

In addition to the JHU nicotine monitor ID number, each monitor will be assigned a nicotine assessment ID number which you will create and write onto a blank label (also supplied by JHU). The nicotine assessment ID number will correctly identify the family, the location where the monitor is being placed (i.e., the map code for the selected room), and the type of the monitor sampling device (e.g., primary, blank, etc.). Therefore, the nicotine assessment ID number will have a three field code consisting of:

- **ETS Study Subject ID#:** This is a seven digit alphanumeric code beginning with an E (e.g., E-A10002).
- **Map Code #:** This is the number of the room as drawn and labeled on the map of the house (e.g., 03).
- **Type of Monitor Being Placed:** Primary = P, Duplicate = D; Field Blank = B; Extra = E; Long Term = LT.
-

An example of a nicotine assessment ID number is **E-A10002-03-P** where:

E-A10002 = SUBJECT ID #

03 = MAP CODE #

P= TYPE OF MONITOR.

Be sure to write the nicotine assessment ID number onto the blank lateral label (before affixing the label to the monitor) with a ball point pen and affix the label to the monitor. **DO NOT** use a felt tip pen because the writing on the label may come off. (NOTE: The JHU team will supply us with a set of labels for us to use with each batch of monitors they send. JHU prefers that we use their labels, since they clean and reuse each monitor, and most commercially available labels cannot be easily cleaned off the monitors. Each label they send will be approximately 1" x ¼.")

4. Initiating the Nicotine Monitor Drop-Off Form

When placing the monitors in the home, you will need to initiate a blank *Nicotine Monitor Drop-Off* form by affixing the appropriate study ID label and indicating the assessment period and date the monitors are being placed in the home at the top of the form. As described in **Section H** below, you will then need to document the placement of each type of monitor in the home by completing the table on page 1 of the *Nicotine Drop-Off Form*. A copy of the *Nicotine Monitor Drop-Off Form* is included at the end of this chapter.

5. Explaining the Air Nicotine Monitors to Participant

Once you have selected the room, and the area within the room where you plan to place the monitors, you will explain to the mother:

- The purpose of the monitor: *"This is an air monitor that measures how much nicotine from cigarette smoking is present in your home. Nicotine from cigarettes stays in the room even after people stop smoking. The monitor contains a sponge filter, and is designed to allow air to flow through the cassette and onto the sponge. We will analyze the sponge to determine the amount of nicotine from cigarette smoke that is in the air that could affect your newborn baby."*
- That the monitors stay in the same location where they were originally placed until they are picked up: *"It is very important the monitors stay in the same location where we are placing them today."*

- That the monitors not be disturbed: *“It is very important that smokers do not touch the air monitors, as any nicotine on their fingers may contaminate the monitors and make it appear that there is more nicotine in the air than there really is. It is also important that children and other family members not touch the monitors because they are very delicate, and they can be damaged easily.”*
- If the monitors fall down, that they be placed back where they were originally located: *“If the monitors fall down, it is best to place them back where they were originally located. If you do ever have to touch the air monitors, please be sure to wear gloves, or socks on your hands, if you do not have gloves. It is best if you pick up the monitor by the clip, and re-hang it if it falls down. You can hold it by the plastic sides. Never touch the screen.”*
- The monitor schedule: *One monitor will be placed and left in the home for the next 7 days, and I will scheduled a time to pick it up. A second monitor will remain in the home for the next 12 months. Both will measure the amount of nicotine from cigarette smoke that is circulating in the air of their homes – one will capture the short-term amount and the other will capture the amount of smoke across the year until your newborn baby is 12 months old.*
- The extra monitor: *I may leave an extra monitor at some of the visits – this will help us make sure that the monitors are working properly.*
- The location of the monitors: *The monitors will be placed in two locations: (1) the room where the baby is most likely to be exposed to smoke or where the baby will spend most of his or her time during the day (if there is no particular room where the baby is most likely to be exposed to smoke or no one smokes inside the house), and (2) the room where the most or second most smoking is likely to occur or the room where household members spend most of their time during the day (if there is no particular room where smoke is most or second most likely to occur or no one smokes inside the home).*

“You said that your baby will spend the most amount of time during the day/evening in [NAME OF ROOM], and s/he will be most likely to be exposed to cigarettes in [NAME OF ROOM]. So, I think we should probably place the first monitor in the [NAME OF ROOM], because that is where the baby spends the most time during the day/evening and will be most likely to be exposed to cigarette smoking. We should place the second monitor in another room, other than where we placed the first monitor, where the most or second most smoking occurs. You said earlier that was the [NAME OF ROOM].”

6. Choose the Location for Placing the Monitors within the Selected Rooms

Monitors must be placed in an area that is representative of the room you want to monitor.

A good location is one that is:

- In an area where the air circulates, but not too close to an exterior window or door going outside, and not too close to an air conditioning or heating vent (where air is being blown into or taken out of the room).
- Where the air monitor sample can hang in the air, at a distance from the floor of approximately 6.5 feet or 79 inches off of the ground.
- In a place that is not too visible to the catch the eye, in order to avoid the possibility that people who see it, will want to touch it. For example, you can place it on the top shelf of a bookcase so long as the windscreen is facing upwards toward the ceiling.
- In a place that is not readily accessible to other older children in the household (who most likely will find this new device interesting, curious, and may want to play with it, touch it, etc), and not located too close to a chair or other object that children can climb up on to reach the monitor.
- Other good places to hang the monitor can be beams, a lampshade, nails in the wall or even plants, again only if they are well above the reach of tallest child living in the home.

A bad location is one that is:

- In an area that is too close to where someone regularly smokes. **DO NOT** place the monitor sampler within 3.5 feet or 39 inches from a sofa, chair or other seating area where someone smokes.
- In an area where the air does not circulate, such as a corner, under a shelf or buried in curtains. **DO NOT** place the monitor in curtains since if they are opened and closed – it will interfere with the monitor functioning properly.

F. Steps for Handling and Placing the Nicotine Monitors in the Selected Rooms/Locations

1. Primary and Duplicate Monitors

As indicated above, the primary monitor will be placed in the room where the baby is most likely to be exposed to cigarette smoke or if no such room exists (e.g., no one smokes inside the home), then the monitor will be placed in the room where the baby is most likely to spend his/her time during the day. If selected for duplicate monitoring, the duplicate monitor will be placed in the home alongside the primary monitor for the entire 7 days. You will pick up the duplicate monitor at the same time you pick up the primary monitor when you return to the home. Steps for handling and placing the primary and duplicate monitors are listed below.

- 1) Put on plastic gloves before opening each monitor.
- 2) Open the plastic container where the monitor is stored, and remove it from the container. Then, remove the monitor from the plastic baggie.

- 3) Handle the monitor carefully and always laterally (i.e., with your thumb and index finger placed firmly around the sides of the plastic container).
- 4) Put the ETS nicotine assessment ID label on the monitor (see *Section E.3* above). To minimize damage, always put the ETS study label on the monitor before you take off the blue cap and cover. The ETS Study label will be placed at the top (lateral side) of the monitor's plastic "filter cassette" (i.e., the filter cassette is the clear plastic part at the top of the monitor). **DO NOT put the label on the windscreen as it will damage the air flow rate into the filter. DO NOT put the label on the Red Cover (BOTTOM) since the covers are removed from the monitor and can be misplaced, fall off, etc.**
- 5) Remove the blue cap (top) first. Removing the blue cap first, allows you to remove the red cover (bottom) without damaging the windscreen. The blue cap helps create a vacuum in the plastic container; making it difficult to remove the red cover. If the blue cap is not removed first, it is possible that the windscreen may be damaged.
- 6) Next, take off the red cover (bottom) carefully. With your thumb and index finger on the filter cassette, slowly twist the red cover away from the plastic container that holds the monitor and filter. **DO NOT try to pry it off with an object such as a key. DO NOT TOUCH IT WITH THE PALM OF YOUR HAND OR FINGERS.** The red cover protects the windscreen, which is not shown in the picture above. It protects the windscreen when it is not in use. Remember, the windscreen, which is directly underneath the red cover is very fragile. The red cover is always removed immediately before placement in the home, and always replaced at the end of the 7 day monitoring period, and must remain in place for storage and shipping.
- 7) Go to the table on page 1 of the *Nicotine Monitor Drop-off Form* and, in the appropriate row and column, immediately write down the date (if not done already) and the exact time you opened the red cover of the primary monitor (and if applicable, the duplicate monitor). Be sure to use a 24-hour time format 0:00 to 24:00. (EXAMPLES: 10AM = 10:00, 12 NOON = 12:00; 2PM = 14:00; 6PM = 18:00).
- 8) Once the red cover (bottom) has been removed, and the time has been recorded, verify that the sampler is complete (i.e., that it has a windscreen, filter, pad and cassette in place, and that the windscreen has not been broken during opening).
- 9) **IF THE WINDSCREEN HAS BEEN BROKEN, DO NOT USE IT.** Cross off the labels, and begin the above steps again with a new air monitor. Put the broken monitor in the plastic container, mark the top of the container with a large "X" for do not use, and take the container back to GWU for storage and separate shipping back to JHU.
- 10) Once the red cover has been removed, and the usefulness of the monitor has been verified, replace the blue top cap. Again holding the plastic monitor by its sides, put the blue cap back onto the top of the monitor before hanging or placing the monitor. The

blue cap is always placed back on before leaving the monitor in the home to collect the air sample.

- 11) Once the monitor has been readied, hang it using the clip at the location selected in the room. You can use the clip to hang the filter (e.g., as described above).
- 12) Always verify to make sure that the monitor is sufficiently fixed so as not to fall off during normal home activities after you leave. If you consider it insufficient, use string or tape to reinforce it (at the clip end only).
- 13) Make sure that the round flat frontal face of the Nucleopore Windscreen on the monitor is facing toward the interior of the room that is being monitored. Make sure that it does not rotate after placement to face a wall or other surface area. **DO NOT lay the monitor flat on a surface (e.g., with the windscreen facing down).**
- 14) Put the red cover inside the plastic bag, and put the bag back into the empty plastic urine cup. Be sure to use a urine cup that DOES NOT have an orange dot sticker. Take the urine cup back to GWU and store it for the seven day interval before returning to the home.
- 15) If a duplicate monitor is being placed, follow the same steps listed above and place the duplicate monitor (without touching the windscreen) by the clip facing toward the interior of the room right next to the primary monitor.
- 16) Be sure you have (a) updated the *Sampling Sheet* to indicate that a primary monitor and duplicate monitor (if applicable) have been placed in the home, and (b) complete items #3-7 for the primary and (if applicable) duplicate monitors in the table on Page 1 of the *Nicotine Monitor Drop-Off Form*.

2. Field Blank Monitor

IMPORTANT: The procedures for placement of the Field Blank Monitor differ from all other monitors. DO NOT use the same procedures for placement of the primary monitor as described above.

As mentioned above, a blank monitor will be collected for 5% of the cases. You will know if the family is selected for blank monitor sampling when you update the *Sample Sheet*. Specifically, if the primary monitor recorded is recorded in a grey-shaded row on the *Sample Sheet* (every 10th case starting with the 5th case), then you will need to collect a blank monitor sample from the home. The blank monitor sample is collected after the primary monitor has been placed and in the same location where you place the primary monitor. Steps for collecting the blank monitor sample are listed below. Also, prior to collecting the blank sample, be sure to create a nicotine assessment ID label for the blank sample (the ID number will end with a “B”) and place the label laterally around the plastic filter cassette part of the monitor (i.e., the filter cassette is the clear plastic part at the top of the monitor). To minimize damage, always put the label on before you take off the blue cap and red cover.

- 1) Take off the Blue Cap (Top), then the Red Cover (Bottom).
- 2) After 2 seconds, immediately replace the red cover and blue cap back on the sampler.
- 3) Go to the table on page 1 of the *Nicotine Monitor Drop-off Form* and, in the appropriate row and column, immediately write down the date (if not done already) and the exact time you opened and closed the red cover of the blank monitor. Be sure to use a 24-hour time format 0:00 to 24:00. (EXAMPLES: 10AM = 10:00, 12 NOON = 12:00; 2PM = 14:00; 6PM = 18:00).
- 4) Place the monitor back into the plastic baggie first. Then, place the baggie into the plastic cup and seal the top for proper storage.
- 5) Place the monitor in the portable refrigerator for transport back to GWU offices.
- 6) Be sure you have (a) updated the *Sampling Sheet* to indicate that a blank monitor has been placed in the home, and (b) complete items #3-8 for the blank monitor in the table on Page 1 of the *Nicotine Monitor Drop-Off Form*.
- 7) DO NOT leave the blank monitor sample in the house.
- 8) Once back at GWU offices, wash hands, put on a new pair of plastic gloves and place the monitors in the refrigerator immediately.

3. Long Term and Extra Monitors

As mentioned above, long-term monitors are being placed to counter the potential reactive effects of periodic home air monitoring. One long-term monitor will be placed in each participant's home during the baseline Home Visit A, and it will remain in that same location for the duration of the study (i.e., until the 12 month assessment).

The long-term monitor is placed in the room where the most cigarette smoke is likely to occur OR if that room happens to be the same room where the baby is most likely to be exposed, the long-term monitor will be placed in the room where the second most cigarette smoking is likely to occur. If no such room exists (e.g., no one smokes inside the home), the long-term monitor is placed in the room where the household members spend most of their time during the day. Although, the long-term monitors look different than the other monitors (i.e., the LT monitors have an orange dot on the urine cups they are housed in, and they have red plugs instead of blue plugs in both the tops and the bottoms of the samplers), the procedures for placing the long-term monitor in the selected room are the same as for the primary and duplicate monitors (see *Section F.1* above).

It is anticipated that the nicotine levels in the room selected for the long-term monitor may differ from the room where the primary monitor is being placed. Therefore, as discussed in *Section C.3* above, during the baseline Home Visit A, you will place an extra monitor next to the

long-term monitor to determine how nicotine levels vary based on their location within the home. **(NOTE: The extra monitor will NOT have an orange dot on the urine cup – it will have a blue top and red bottom just like the primary, blank and duplicate monitors.)** This will inform us as to how levels vary in the two most likely areas for placement in the home where the infant could be exposed to environmental tobacco smoke. Differential levels of household ETS exposure (vis a vis ambient nicotine levels) in these rooms could affect our decisions regarding the best location for placement during the main study.

During Home Visit A for the postpartum visits, the location of the extra monitor may change. Again, if the mother indicates in the postpartum version of the *Nicotine Monitor Placement and Safety Observation Determination Form* that the room where the baby spends most of his or her time during the day (Q. #17) has changed since baseline OR the room where the baby is most often exposed to cigarette smoke (Q. #20) has changed since baseline, then the placement of the extra monitor will be in the new room. If both of these rooms have changed, and the rooms do not match each other (i.e., the mother gives different responses for both Q. #17 and Q. #20), then place the extra monitor in the new room where the baby is most likely to be exposed to cigarette smoke (Q. #20).

Also, be sure you have completed items #3-7 for the long-term and extra (if applicable) monitors in the table on Page 1 of the *Nicotine Monitor Drop-Off Form*.

G. Removal of Monitors from the Home and Transport to GWU

1. Primary, Duplicate, and Extra Monitors

During Home Visit B (i.e., at the end of the 7 day monitoring period), you will need to pick up the monitors from the home. To remove the samples from the home, follow the steps listed below.

- 1) Initiate a *Nicotine Monitor Pick-Up Form* (see **Section H** below) by affixing the appropriate study ID label and indicating the assessment period and date the monitors are being placed in the home at the top of the form.
- 2) Remove the primary monitor and if applicable, duplicate and extra monitors, from their location and carefully replace the plastic red cover (bottom) back onto each monitor.
- 3) Immediately write the date and time when the red cover (bottom) is replaced onto the monitor on the *Nicotine Monitor Pick-Up Form*. Always use a 24-hour time format 0:00 to 24:00. (EXAMPLES: 10AM = 10:00, 12 NOON = 12:00; 2PM = 14:00; 6PM = 18:00) when you write down the date and time you opened the filter on the sampling sheet.
- 4) Verify that each monitor remained in the same place across the 7 day monitoring interval—at the same place as it was originally placed and document in item #8 on *Nicotine Monitor Pick-Up Form*.

- 5) Verify the correct identification of the JHU monitor ID number and ETS nicotine assessment ID number (i.e., the ETS Subject ID #, Map Code #, and the Type of Monitor) with the information recorded on the *Nicotine Monitor Drop-Off Form*.
- 6) Complete items #4-9 on the *ETS Nicotine Monitor Pick-Up Form* in the appropriate column for each monitor you collect.
- 7) Place the monitor back into the plastic baggie first. Then, place the baggie into the plastic cup (be sure to use a cup that DOES NOT have an orange dot sticker) and seal the top for proper storage.
- 8) Place the monitor in the portable refrigerator for transport back to GWU offices.
- 9) Before leaving the home, verify that the LT monitor is still in its place. If it is not in place, replace it with a new LT monitor. (Note: For the 12-month assessment, you will collect the long-term monitor as described in **Section G.2** below). Complete items #4-9 on the *ETS Nicotine Monitor Pick-Up Form* for the long-term monitor (Column D).
- 9) Once back at GWU offices, wash hands, put on a new pair of plastic gloves and place the monitors in the refrigerator immediately.
- 10) Enter required information from *Nicotine Monitor Drop-off and Pick-Up Forms* into the most current *JHU Monitor Shipping and Results Spreadsheet* (discussed in **Section H.3** below).

2. Removal of Long-Term Monitor (at 12 month assessment)

At Home Visit B for the 12-month assessment, you will also pick up the **long-term monitor**. Follow these steps when picking up the long-term monitor.

- 1) Verify that the monitor remained in the same place across the 12 month interval—at the same place as it was originally placed.
- 2) Verify the correct identification of the JHU monitor ID number and ETS nicotine assessment ID number (i.e., the ETS Subject ID #, Map Code #, and the Type of Monitor) with the information recorded on the *Nicotine Monitor Drop-Off Form*.
- 3) Remove the long Term monitor from its location and carefully replace the plastic red cover (bottom) back onto the monitor.
- 4) Immediately write the date and time when the red cover (bottom) is replaced onto the monitor in the table on Page 1 of the *Nicotine Monitor Pick-Up Form*.
- 5) Place the monitor back into the plastic baggie first. Then, place the baggie into a plastic urine cup that DOES have an orange dot sticker and seal the top of the urine cup for proper storage.

- 6) PUT A LABEL ON THE URINE CUP OF THE LONG TERM MONITORS SO THEY ARE NOT REUSED. Write LTM on a label in large letters, and place the label on the top of the urine cup so the monitor will NOT be sent to JHU for processing.
- 7) Place the long term monitor in a separate box or plastic bag for transport back to GWU for re-use.
- 8) Always keep the long term monitors separate from the primary, duplicate, extra, and blank monitors.
- 9) **DO NOT** place the monitor in the portable refrigerator for transport back to GWU offices.
- 10) Once back at GWU offices, place the long-term monitor from the 12 month visit assessment in a separate box clearly labeled as a long-term monitor ONLY.
- 12) The long term monitors will be sent back to JHU for recycling in other ETS Study participant homes. They will not be analyzed. They will need to be shipped back to JHU on a regular basis as they are picked up.

H. Completing the Nicotine Monitor Forms and JHU Monitor Shipping and Results Spreadsheet

1. Nicotine Monitor Drop-Off Form

Each time you place a nicotine air monitor sample in the home, you will need to complete a *Nicotine Monitor Drop-Off Form*. An example of a completed form is included at the end of this chapter. As described above, this form is initiated prior to placing the monitors in the home by affixing the appropriate study ID label and indicating the assessment period and date the monitors are being placed in the home at the top of the form. Also, when you open the air monitors, you will need to immediately record the time the monitors were opened in the table on Page 1 of this form (see item #7). Further instructions for completing this form are listed below.

1. **Assessment Period:** Mark the appropriate assessment period. Nicotine monitors will always be placed in the home during Home Visit A.
2. **Monitor Drop-Off Date:** If no monitors are placed in the home, indicate the date of the home visit assessment and then check the box marked “NO MONITORS DROPPED OFF,” and be sure to explain the reason in the space provided. If monitors were placed in the home, continue by completing items #3-8 (in the table on page 1) for each type of monitor.
3. **Was this monitor placed?** For each type of monitor listed in columns A-F, indicate whether or not the monitor was placed in the home. If a monitor was placed in the home, continue with items #4-8 for that monitor; otherwise, skip to the next column.

4. **JHU Monitor ID #:** Indicate the unique monitor ID number assigned by JHU to each monitor placed in the home. This ID number will already be affixed to each monitor upon receiving the monitors from JHU.
5. **Map Code #:** Indicate the map code number assigned to the room where each monitor is placed; the map code number is the *unique number assigned to each room* in the house when completing the drawing of the household map. Refer to either the household map or the table on page 2 of the Nicotine Monitor Placement/Safety Observation Form for this number. Do NOT confuse the Room Code # with the Map Code #. A room will retain the same Map Code # for the duration of the study, whereas the Room Code # may change – because the family name for a room may change during the study (e.g., the second bedroom becomes the family room).
6. **Room Code #:** Indicate *the room code number characterizing the type of room* (e.g., code 04=living room/dining room); this information can be obtained from the table on page 2 of the *Nicotine Monitor Placement and Safety Observation Determination Form* at each subsequent visit.
7. **Time Opened:** When placing the monitor in the selected location within the room, immediately record the time the exact time you opened the red cover (bottom) of each monitor. Be sure to use a 24-hour time format 0:00 to 24:00. (EXAMPLES: 10AM = 10:00, 12 NOON = 12:00; 2PM = 14:00; 6PM = 18:00).
8. **Time Closed:** If a **blank monitor** sample is collected (this will be done for 5% of all cases), indicate the exact time you closed the red cover (bottom). Be sure to use a 24-hour time format 0:00 to 24:00.
- 9/10. **Primary/Long-term & Extra Monitor Room Diagram:** In the space provided, diagram any doors or windows and the location of the monitor within the room and complete items a-f.
 - a. **Map Code #:** This is the unique code number assigned to the room on the drawing of the household map.
 - b. **Number of (I) Doors:** Indicate the number of doors within the room that open to an *indoor* environment (e.g., another room or closet).
 - c. **Number of (O) Doors:** Indicate the number of doors within the room that open to an *outdoor* environment.
 - d. **Number of (I) Windows:** Indicate the number of windows within the room that open to an *indoor* environment (e.g., another room).
 - e. **Number of (O) Windows:** Indicate the number of windows within the room that open to an *outdoor* environment.
 - f. **Type of Air Conditioning System:** Check the appropriate box to indicate if the air conditioning is central (runs throughout the entire house), window (you should see an air conditioning unit at one of the windows within the room), or if there is none at all.

To draw and label doors and windows in the room, use the symbols provided in the legend below items #9 and 10 to indicate clearly where the windows and doors are located within the room. Mark all doors and windows as shown in the example form included at the end of this chapter. If the door or window opens to an indoor environment, add an “I” in parentheses under the symbol, and if the door or window opens into an outdoor environment add an “O” in parentheses directly under the symbol. Write the number of doors and windows opening into inside rooms or into outside spaces on the appropriate lines.

Then use the symbol “X” to indicate clearly where the monitors are located in the room. Indicate the type of monitor placed in the room in parentheses after the “X,” (e.g., P= primary monitor, LT = long-term monitor; and E=extra monitor).

Example: X – P, D if the primary and duplicate were placed.

11. **Is the Long-Term Monitor in the same location as the last visit?** This question only applies to the post-partum assessments; for the baseline assessment, check the N/A box.
12. **Monitors dropped off by:** Write your name (the home visitor) in the space provided.
13. **Comments:** As appropriate, provide any additional comments regarding the nicotine monitor drop-off procedure.

2. Nicotine Monitor Pick-Up Form

Each time you return to the home to pick up a nicotine air monitor from the participant’s home (i.e., during Home Visit B), you will need to complete a *Nicotine Monitor Pick-Up Form*. An example of a completed form is included at the end of this chapter. This form is initiated prior to picking up the monitors by affixing the appropriate study ID label and indicating the assessment period and date the monitors are being picked up from the home at the top of the form. Also, when you pick up each monitor and close the red cover (bottom) as instructed above, you will need to immediately record the time the monitors were closed in the table on Page 1 of this form (see item #9). Further instructions for completing this form are listed below.

1. **Assessment Period:** Mark the appropriate assessment period. Nicotine monitors will always be picked up from the home during Home Visit B.
2. **Monitor Pick-Up Date:** If no monitors are picked up from the home during the home visit, indicate the date of the home visit assessment and then check the box marked “NO MONITORS PICKED UP,” and be sure to explain the reason in the space provided. If monitors were picked up from the home, continue by completing items #3-9 (in the table on page 1) for each type of monitor.
3. **Did you check this monitor?** This item applies only to the long-term monitor.

4. **Was this monitor picked up?** For each type of monitor listed in columns A-B and D-F, indicate whether or not the monitor was picked up from the home. If a monitor was picked up from the home, continue with items #5-9 for that monitor; otherwise, skip to the next column.
5. **JHU Monitor ID #:** Indicate the unique monitor ID number assigned by JHU to each monitor placed in the home. This ID number will already be affixed to each monitor upon receiving the monitors from JHU.
6. **Map Code #:** Indicate the map code number assigned to the room where each monitor is picked up from; the map code number is the *unique number assigned to each room* in the house when completing the drawing of the household map. Refer to the nicotine assessment ID label affixed to the monitor for this number.
7. **Room Code #:** Indicate *the room code number characterizing the type of room* (e.g., code 04=living room/dining room); this information can be obtained from either the Nicotine Monitor Drop-Off Form or the table on page 2 of the *Nicotine Monitor Placement and Safety Observation Determination Form*.
8. **Same location in room?** Indicate whether or not you picked up the nicotine monitor from the exact location where you initially placed the monitor during Home Visit A. Verify that the room is the same room marked for the monitor on either the household map or the table on page 2 of the *Nicotine Monitor Placement and Safety Observation Determination Form*.
9. **Time Closed:** When collecting each monitor, immediately record the time the exact time you closed the red cover (bottom) of each monitor. Be sure to use a 24-hour time format 0:00 to 24:00. (EXAMPLES: 10AM = 10:00, 12 NOON = 12:00; 2PM = 14:00; 6PM = 18:00).
10. **Were there any problems collecting air monitor (e.g., did they drop while you were holding them, was the windscreen facing out into the room, did you forget to use gloves, etc.)?** If yes, describe in detail the problems encountered picking up the monitors.
11. **Did participant have any problems with the air monitors during the time interval (e.g., did they fall down, did someone touch them, did the children play with them, etc.),?** Ask the participant if she had any problems with the monitors during the past week, and if so, explain.
12. **Monitors collected by:** Write your name (the home visitor) in the space provided.
13. **Comments:** As appropriate, provide any additional comments regarding the nicotine monitor drop-off procedure.

3. JHU Monitor Shipping and Results Spreadsheet

As discussed in *Section J* below, nicotine monitors will be sent to JHU for analysis in batches of 40-50 monitors. Each time a batch of monitors is sent to JHU for analysis, you will also need to send (via email) a *JHU Monitor Shipping and Results* spreadsheet which includes information for each monitor included in the batch. Information to be entered into the spreadsheet (which can be obtained from the Nicotine Monitor Drop-off and Pick-up forms) includes: JHU monitor ID #, ETS subject ID #, map room #, type of monitor, date and time placed in the home, date and time removed from the home. An example spread sheet is included at the end of this chapter. This information should be entered into the spreadsheet immediately after completing Home Visit B when you collect the nicotine monitors. Note that the long-term monitors DO NOT need to be included in the spreadsheet.

Once 50 nicotine monitors have been collected and entered into the spreadsheet, you can “close out” the spreadsheet and send the monitors (along with the spreadsheet) to the staff at JHU. A new *JHU Monitor Shipping and Results Spreadsheet* will then be created for the next batch of monitors collected from the field. Once JHU analyzes the monitors, they will enter the results of the monitors into the *JHU Monitor Shipping and Results Spreadsheet* and email the file back to you.

To help keep track of shipments and results received, file names for the spreadsheets will be sequentially numbered and indicate the shipment date or the date results were received. For example, the file name for the first shipment of monitors would be “JHUMONITORSHIPMENT01(SENT 12-2-05).” Once you receive the completed spreadsheet from JHU (i.e., the spreadsheet containing the results), you will save the file in the same directory on your computer where you stored the original file, and you will rename the file as “received” and indicate the date the file was received from JHU. For example, you would save and rename the file mentioned above as “JHUMONITORSHIPMENT01(RECEIVED 12-23-05).”

I. Storage and Handling of the Air Monitor Samplers:

1. Primary, Duplicate, Extra, and Blank Air Monitor Samples

Proper storage of monitors is critical to the quality of data collected.

- The air monitor samplers will be stored in a smoke free environment at GWU prior to placement in participant homes.
- Always handle monitors using plastic gloves which have not been contaminated by nicotine. Home visitors should be careful when handling all monitors and collection supplies since nicotine may be on their person (fingers, clothes etc) before, during and after leaving participant homes. This is true whether or not they smoke.
- Discard used gloves before you leave the home (after dropping off and picking up monitors), and in a trash receptacle outside of the GWU office where the monitors are being stored.

- During the 7 days in between home visits, store the empty urine cups (with baggie and red cover inside) in either the tool kit or the GWU offices, but the correct urine cups (e.g., with or without orange dots) will need to be taken back to the home during the second visit of each assessment period.
- Once monitors have been collected from participant homes, the monitors will be immediately placed in a portable refrigerator for transport back to GWU offices (e.g., they will not be stored overnight at the Home Visitors home or in his/her car).
- During transport, the portable refrigerator will always be powered by the car battery (e.g., cigarette lighter) to maintain proper temperatures. The portable refrigerators should be stocked with blue ice packs as well, should there be any time that the car battery is not operative during transport.
- Once at GWU, all short-term monitors (e.g., the primary, duplicate, blank, and extra monitors) will be stored in a 4 degree temperature refrigerator in the GWU offices prior to shipment to JHU.
- Both the portable and the GWU office refrigerators should have a BIOHAZARD SYMBOL on them, and a warning label. Neither refrigerator is to be used to store food, drinks or other products other than the urine, saliva, and nicotine monitor biomarker specimens.
- Primary, blank, duplicate, and extra monitors will be sent ASAP to JHU for processing.
- Shipment to JHU will occur in batches of 10 or 20 monitors, depending on how quickly they are being collected.

2. Storage and Handling of Long Term Monitors

Be aware that when picking up the long-term monitors, they **MUST BE KEPT SEPARATE FROM OTHER MONITORS**. Therefore, used long-term monitors will need to be stored separately from the primary, duplicate, blank, and extra monitors at the GWU offices. They do not need to be refrigerated. They should always be placed in urine cups with an orange dot on them to distinguish them from other monitors. They should be kept in boxes in the GWU offices separate from the primary, duplicate, blank, and extra monitors.

Long-term monitors will also be shipped back to JHU separately from the other monitors. They will be shipped back to JHU for recycling (but not for processing) because if they sit in the GWU offices, they might somehow contaminate the other monitors. Also, JHU can use additional monitors for other studies. They will need to be stored in boxes separate from the unused monitors so as not to reuse them.

J. Shipment of the Air Monitor Samplers

Batches of samples can be sent from GWU to JHU by mail. Mailing arrangements will be coordinated by the Home Visitor, with the assistance of the Field Coordinator, Prag Katta, and the JHU point of contact. Steps for shipping the monitors to JHU are listed below.

1. Nicotine monitors will be sent to JHU in batches of 40-50 monitors. An email should be sent to inform JHU that a batch of samples is coming. A confirmation should be received from JHU before sending a shipment.
2. As discussed above in **Section H.3**, a *JHU Monitor Shipping and Results Spreadsheet* should be attached to the email with sample information including the JHU monitor number, ETS subject ID#, date and times for nicotine monitor drop-off and pick-up in order for JHU to calculate nicotine concentrations.
3. The batch of air monitor samples to be processed by JHU must be shipped from GWU to JHU using **overnight delivery for delivery before noon. Dry ice is NOT needed.** A copy of the spreadsheet print-out for that shipment of monitors should be included in the box.
4. Make sure to ship for delivery on a week day; **DO NOT** send shipments on a day before the weekend or before a holiday.
5. Send shipments at the end of a day – so that they sit in storage less time before delivery.
6. Remember, GWU holidays may differ from those at JHU.
7. Always double-check by placing a phone call to D'Ann Williams in advance of shipping monitors. Verify that she or someone will be at JHU to receive and store them quickly in a refrigerated area. Provide her with an estimated time of delivery (e.g., 10:30AM or before Noon is preferred).
8. The **long-term monitors** can be shipped **regular mail** and should be shipped separately. A **RECYCLING MEMORANDUM** should be included in the box.
9. Samples need to be sent to the following **Johns Hopkins University Point of Contact:**

D'Ann Williams, MS
Research Technician
Johns Hopkins School of Public Health
Environmental Health Engineering
W6106 Wolfe St. Bldg.
615 N. Wolfe St.
Baltimore, MD 21205
410-614-5755
FAX 410-955-9334
dlwillia@jhsph.edu

10. JHU will analyze monitors in batches of 40-50 monitors – our samples will be combined with others in the analysis so they can be processed more quickly.
11. JHU will return nicotine data following analysis with the results typed into the *JHU Monitor Shipping and Results Spreadsheet*. As discussed in **Section H.3** above, once you receive the completed spreadsheet from JHU (i.e., the spreadsheet containing the results), you will save the file in the same directory on your computer where you stored the original shipping file, and you will rename the file as “received” and indicate the date the file was received from JHU. The “received” files will then be sent to RTI for data analysis activities.

K. Log Information from Collected Monitors into the DMS & JHU Monitor Shipping and Results Spreadsheet

As discussed in **Chapter II** of this manual, at the end of each home visit, you will need to document the completion of all home visit activities (including the nicotine monitor drop-off and pick-up activities) in *Home Visit Activities Booklet*. You will enter information from this booklet into the DMS immediately upon returning to the GW office.

You will also need to enter the following information from the *Nicotine Monitor Drop-Off and Pick-Up* forms into the *JHU Monitor Shipping and Results Spreadsheet* which will be sent to JHU when you send the monitors for processing.

- JHU Monitor ID #
- Map Room #
- Type of Monitor
- Date Placed in Home
- Time of Day
- Date Removed from Home
- Time of Day

After entering the required information into the *JHU Monitor Shipping and Results Spreadsheet*, the *Nicotine Monitor Drop-Off and Pick-Up Forms* will be sent to RTI for data entry.

L. Summary of Nicotine Monitor Procedures

1. Pick up appropriate supplies and home visit air monitor kit and materials before going to home.
2. Select the rooms for placing the primary and long-term monitors based on mother’s answers to the baseline version of the *Nicotine Monitor Placement and Safety Observation Determination Form*.

3. Complete/update *Nicotine Monitor Sampling Sheet* to determine the need for a blank or duplicate monitor.
4. Create ETS nicotine assessment ID numbers and labels for each type of monitor being used in the home; place the corresponding label on each monitor.
5. Initiate the *Nicotine Monitor Drop-Off Form*.
6. Explain the purpose and use of the nicotine monitors to the participant.
7. Evaluate each selected room and determine location for nicotine monitor.
8. Place the sampler:
 - Open the plastic cup and handle carefully the monitor
 - Document the JHU ID number in item #4 of the *Nicotine Monitor Drop-Off Form*.
 - Affix nicotine assessment ID label laterally onto the side of the plastic filter cassette.
 - Remove the Blue Cap (TOP), then Red Cover (BOTTOM).
 - Replace Blue Cap (TOP) before hanging.
 - Put Red Cover (Bottom) in plastic baggie, and back in plastic cup and take with you.
 - BEFORE HANGING the sampler and assure THAT the SAMPLER IS WELL PLACED, SECURE AND FIXED IN POSITION.
9. Complete all remaining information on the *Nicotine Monitor Drop-Off Form*.
10. Do not forget to place the duplicate (and extra and long-term monitors) in their assigned places or collect the blank sample as per protocol.
11. Return one week later (Home Visit B) to pick up the nicotine monitors (all but the long-term monitor which is removed from the home during Home Visit B of the 12 month assessment). Complete *Nicotine Monitor Pick-Up Form*.
12. Enter information from *Nicotine Monitor Drop-off and Pick-Up Forms* into the *JHU Monitor Shipping and Results Spreadsheet*.
13. Store monitors at GW and ship to JHU for processing along with *JHU Monitor Shipping and Results Spreadsheet*. When picking up the long-term monitors or sending to JHU, be sure to keep them **SEPARATE FROM ALL OTHER MONITORS**; also, long-term monitors SHOULD NOT be included in the *JHU Monitor Shipping and Results Spreadsheet*.

INSERT THE FOLLOWING FORMS:

Nicotine Monitor Sample Sheet

Nicotine Monitor Drop-Off Form

Nicotine Monitor Pick-Up Form

Nicotine Monitor Shipping and Results Spreadsheet